

Home Medical Device Retailer (HMDR) Frequently Asked Questions:

Q) What is an HMDR business and who needs an HMDR license from the DHS, Food and Drug Branch?

A) A Home Medical Device Retail (HMDR) **facility** is defined as any area, place, or premises [other than a licensed pharmacy] **in and from which** prescription (Rx) devices, home medical devices, or home medical device services are stored, sold, rented, furnished, or dispensed pursuant to a prescription **at retail**. An HMDR **warehouse** is a separate place where prescription (Rx) devices, home medical devices, or home medical device services are stored and transported to the **retail facility** (NOT direct to patients' homes).

Any person conducting an HMDR business (retail facility or warehouse) in the State of California must first obtain a license from DHS/FDB. A separate license is required for each premise. The license must be renewed annually, and is non-transferable.

An **Out-of-State** HMDR facility is a business outside California that sells or distributes **prescription (Rx)** medical devices in this state by **retail**. Out of state facilities sending products into California residents must obtain a HMDR Registration. {FYI: **Wholesalers of medical devices and equipment are not required to obtain a HMDR license/registration, but may be required to register with the Board of Pharmacy if they distribute prescription (Rx) devices for wholesale purposes**}

Q) Where can I get an HMDR license application and what are the fees?

A) Applications are available online at: www.dhs.ca.gov/fdb

The license fees for HMDR **facilities** in California are \$850 per location per year. The license fee for a warehouse located in California is \$425 per location per year. The **out-of-state** registration fee is \$150 per year.

Q) Are there exceptions to the kinds of facilities that are required to have an HMDR license?

A) Yes. Some exemptions include physicians' offices, veterinarians, dentists, pharmacies, manufacturers and wholesalers that sell to hospitals or nursing homes, orthotics and prosthetics retailers.

Q) What is the licensing process and how long does the process take?

A. Once the HMDR license application and fees are processed through DHS Accounting, the application is sent to FDB for review. A properly completed HMDR facility license application is then assigned to an investigator in the closest geographic area. The licensing process time depends on the readiness of the firm and the investigator's current case load. On average, a ready firm, with a suitable facility, trained staff, and complete policies, procedures, and records is licensed within 3 months from date FDB received the application. The date of issuance is recorded as of the date you passed inspection and you may legally begin operating as of that date.

Q) Can I operate my HMDR business without a valid license?

A) No. It is illegal to begin operations of the HMDR business without a valid HMDR license.

State and federal healthcare programs require you to submit a copy of this license before they process provider or supplier applications.

Q) After my facility is inspected, how long afterwards must I wait for my facility license?

A) The actual license certificate is usually issued and mailed within two-three weeks after your facility successfully passes the inspection.

Q) If my facility fails to meet compliance standards, what happens?

A) Your facility will have a period of time within which to correct any deficiencies noted on the Report of Observations. Depending on the significance of the deficiencies, the investigator may review mailed-in/faxed documents as proof of correction, or re-inspect the facility to verify compliance. If compliance cannot be reached, you may be issued a denial letter stating grounds for denial and process for appeal.

Q) If I move or sell my business, can my license be transferred?

A) **NO.** The HMDR license is not transferable. A change of address or a change in ownership (including incorporation) requires that the facility submit a new application with new fees regardless of when the existing license is due to expire. If you fail to notify FDB, you are conducting business illegally and your ability to bill Medi-Cal and or Medicare may be jeopardized.

Q) What is a Temporary License, and what are the criteria for receiving one?

A) A firm in good compliance standing with FDB may be eligible for a temporary license. Upon notification of a re-location or change of ownership, FDB may elect to send a supplemental questionnaire which can be completed and notarized. FDB Staff will review the questionnaire and facility history for compliance, and if approved, a Temporary HMDR license will be issued - valid for one year. A verification inspection will follow to ensure the firm is in compliance. Then the temporary license will be replaced with the renewable license.

Q) What are dangerous or “legend” devices?

Dangerous or legend devices may also be referred to as prescription or Rx devices.

These are devices that bear a label stating: “Caution --Federal law prohibits the dispensing of this product without a valid prescription from a physician...” Legend devices cannot be sold over-the-counter (OTC), but can only be dispensed by an authorized healthcare professional, including an HMDR exemptee.

Examples of legend devices include: ***Oxygen, Respiratory equipment (O2 concentrators, nebulizers, mask and tubing) TENS units, Enteral feeding kits, syringes, CPAP machines, catheters.***

Q) I wish to dispense legend medical devices from my HMDR. Do I need a special license?

A) Yes. In order to dispense legend devices your facility must employ either a pharmacist, a pharmacist in charge (PIC), or a licensed HMDR exemptee.

Q) How can I obtain an HMDR exemptee license?

A) A licensed HMDR operator may submit an exemptee license application for an employee that meets the required knowledge and training mandated by California Health and Safety Code 111656.4. This law requires one year of lawful work experience, evidence of successful completion of high school, and evidence that the applicant has completed a training course that addresses areas of knowledge and training. The initial license application requires a non-refundable fee of \$100 to cover the review and processing of the application, and \$150 for issuance of the actual license renewable annually.

The applicant must be an employee of the facility. Evidence of employment will be verified.

Q) Can I obtain an exemptee license without working at a HMDR facility?

A) No. An exemptee must be employed by a HMDR facility. If the exemptee ceases to be employed by the HMDR facility, the license becomes inactive, or may be transferred to another licensed HMDR facility with proof of exemptee employment.

Q) What about HMDR renewal inspections? How frequently are they conducted, and what are some common violations found?

A) Renewal inspections can take place annually, unannounced, at any HMDR facility during normal business hours. A customer complaint or other referral may trigger an inspection.

Common violations reported include: ***Dispensing legend devices without a valid HMDR exemptee on premise; Lack of dispensing records for legend devices; Inadequate procedures for the cleaning and repair of rental devices; Inadequate staff training or patient/caregiver consultation; Inadequate record of complaints or review of customer complaints to prevent reoccurrence.***

Q) How can I get a copy of the HMDR Law and/or guidance on requirements?

A) Information regarding the HMDR licensing System can be found in California Health and Safety Code Sections 111656 through 111656.13, **Sherman Food, Drug, and Cosmetic Law**, which can be found on the Internet at: **www.dhs.ca.gov/fdb**.